UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

SHARON BRODIE, Surviving Spouse and Executor of the Estate of JOHN BRODIE, Deceased,	:	
Plaintiff,	:	
	:	Case No. 4:10-CV-00138 (HEA)
v.	:	
NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Defendant.	:	

PLAINTIFF SHARON BRODIE'S MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION FOR JUDGMENT AS A MATTER OF LAW

Plaintiff Sharon Brodie ("Mrs. Brodie" or "Plaintiff") respectfully submits this memorandum of law in opposition to defendant Novartis Pharmaceuticals Corporation's ("NPC" or "Defendant") motion for judgment as a matter of law pursuant to Rule 50(a) of the Federal Rules of Civil Procedure.

Because the evidence introduced by Plaintiff at trial is more than sufficient to meet her burden of proof on the claims she asserts, Defendant's Rule 50 motion should be denied. More specifically, and contrary to Defendant's arguments, Plaintiff has introduced more than sufficient evidence for a reasonable jury to find that (i) Defendant's August 2004 Zometa Label failed to adequately warn that Zometa causes osteonecrosis of the jaw ("ONJ") and (ii) Defendant's failure to warn was the proximate cause of John

Brodie's injuries. Most notably, when Dr. Schultz, the physician who prescribed Zometa to John, had a second chance to prescribe Zometa, he did not do so.

ARGUMENT

I. Motions For Judgment As A Matter Of Law

Rule 50 of the Federal Rules of Civil Procedure allows a district court to resolve an issue against a party and to grant a motion for judgment as a matter of law if the court finds that "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a). As the Court of Appeals for the Eighth Circuit has explained:

> To sustain an entry of judgment as a matter of law, "[t]he evidence must point unswervingly to only one reasonable conclusion. This demanding standard reflects our concern that, if misused, judgment as a matter of law can invade the jury's rightful province."

Penford Corp. v. National Union Fire Ins. Co., 662 F.3d 497, 503 (8th Cir. 2011) (quoting *Gardner v. Buerger*, 82 F.3d 248, 251 (8th Cir.1996)); see also, *Howard v. Missouri Bone & Joint Ctr., Inc.*, 615 F.3d 991, 995 (8th Cir. 2010); *Duke v. Gulf & Western Mfg. Co.*, 660 S.W.2d 404, 409 (Mo. App. W.D. 1983) ("Sustaining a motion for a directed verdict is a drastic action and should only be done when all the plaintiff's evidence and reasonable inferences which may be drawn therefrom are so strongly against the plaintiff that reasonable minds cannot differ.").

In reviewing a motion for judgment as a matter of law, the district court must draw all reasonable inferences in favor of the nonmoving party in this case, Mrs. Brodie. See *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 151 (2000); *Phillips v. Collings*, 256 F.3d 843, 847 (8th Cir. 2001). The district court may not make credibility

determinations or weigh the evidence. *Id*. Those functions are exclusively for the jury, not the judge. *Id*. While the district court necessarily reviews the record as a whole:

> it must disregard all evidence favorable to the moving party that the jury is not required to believe. That is, the court should give credence to the evidence favoring the nonmovant as well as that evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that that evidence comes from disinterested witnesses.

Phillips v. Collings, 256 F.3d 843, 847 (8th Cir. 2001) (quoting *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 151 (2000)).

The decision whether to grant a motion for judgment as a matter of law lies within the district court's discretion. *Unitherm Food Sys., Inc., v. Swift–Eckrich, Inc.*, 546 U.S. 394, 399 (2006). As Rule 50(a) states, the court "may" grant judgment as a matter of law. Fed. R. Civ. P. 50(a). In fact, "while a district court is permitted to enter judgment as a matter of law when it concludes that the evidence is legally insufficient, it is not required to do so. To the contrary, the district courts are, if anything, encouraged to submit the case to the jury, rather than granting such motions." *Unitherm Food Sys., Inc., v. Swift–Eckrich, Inc.*, 546 U.S. 394, 405 (2006). As the Supreme Court explained, for example:

> Even at the close of all the evidence it may be desirable to refrain from granting a motion for judgment as a matter of law despite the fact that it would be possible for the district court to do so. If judgment as a matter of law is granted and the appellate court holds that the evidence in fact was sufficient to go to the jury, an entire new trial must be had. If, on the other hand, the trial court submits the case to the jury, though it thinks the evidence insufficient, final determination of the case is expedited greatly. If the jury agrees with the court's appraisal of the evidence, and returns a verdict for the party who moved for judgment as a matter of law, the case is at an end. If the jury brings in a different verdict, the trial court can grant a renewed motion for judgment as a matter of law. Then if the appellate court holds that the trial court was in error in its appraisal of the evidence, it can reverse and order judgment on the verdict of the jury, without any need for a new trial.

Id. at 405-06 (quoting Wright and Miller, 9A Federal Practice § 2533, at 319).

II. Defendant's August 2004 Zometa Label Did Not Adequately Warn Of The Risk Of ONJ

In general, "[w]hether or not a given warning is sufficient depends upon its placement or location, the language used and how it may or may not impress the average user." *Tennis v. General Motors Corp.*, 625 S.W.2d 218, 226 (Mo. App. S.D. 1981); see also, *Grady v. American Optical Corp.*, 702 S.W.2d 911, 917 (Mo. App. E.D. 1985) (quoting *Tennis*). Presently, the only evidence before the Court and the jury proves that Defendant's August 2004 Zometa Label was inadequate to warn of the risk of ONJ.

Plaintiff presented the testimony of Dr. James Vogel. Tr. Vol. 4 at 7-71. Dr. Vogel is board certified in internal medicine, medical oncology and hematology. *Id*. at 11:24-12:1. He has been in practice for almost forty years. *Id*. at 11:1-2. Dr. Vogel is familiar with bisphosphonates generally and Zometa in particular. *Id*. at 15:20-22, 17:8-16. As a medical oncologist, he prescribes bisphosphonates. *Id*. at 16:24-17:3. Dr. Vogel is familiar with the August 2004 Zometa Label, the label at issue in this case, as well as the September 2004 Dear Doctor Letter. *Id*. at 22:12-24:23. Dr. Vogel was offered as an expert in the fields of hematology and medical oncology and, without objection, accepted by the Court. *Id*. at 17:17-20.

Osteonecrosis of the jaw is not referenced in the "Warnings" section of the August 2004 Zometa Label. *Id*. at 23:7-18; see also Plaintiff's Exhibit PX 1178 (the 2004 Zometa Label). Accordingly, any analysis of the Label begins in the "Precautions" section and/or the "Adverse Events" section. Those sections were dissected during Dr. Vogel's testimony.

With respect to those sections, Dr. Vogel testified that, in his opinion, the August 2004 Zometa Label did not adequately inform prescribing physicians about the risk of ONJ. *Id*. at 25:13-20, 26:6-13. Dr. Vogel testified that the August 2004 Zometa Label was inadequate because it: (i) failed to mention any causal association between Zometa and ONJ (*Id*. at 27:3-28-16, (ii) it failed to mention that there were spontaneous cases of ONJ, not associated with an invasive dental procedure (*Id*. at 29:22-32:21), and (iii) the "multiple well-documented risk factors" for ONJ identified in the Label are neither well-documented nor risk factors for ONJ (*Id*. at 38:5-40:7). Finally, Dr. Vogel explained that the 2004 Dear Doctor Letter included the same inadequate and misleading language as the August 2004 Zometa Label. Tr. Vol. 4 at 23:19-24:23.

Ignoring Dr. Vogel's testimony entirely, Defendant seems to suggest that this Court should find the August 2004 Zometa Label adequate as a matter of law simply because it mentions osteonecrosis of the jaw in two sections. None of the cases relied on by Defendant, however, supports its argument. In those cases, there were clear and specific warnings or directions directly on point. That is not the case here. In any event, even if this Court were to find that the language in the August 2004 Label is a warning about the risk of ONJ, Dr. Vogel's testimony creates an issue properly left to the jury. See *McGeoghegan v. SPX Dock Prods., Inc.*, No. 4:04–CV–1270 CEJ, 2006 WL 416088 *4 (Feb. 21, 2006 E.D. Mo.) ("Whether or not th[e] duty [to warn] was adequately discharged . . . is a question for the jury.")

Because Plaintiff has introduced more than sufficient evidence for a reasonable jury to decide that Defendant did not adequately warn of the risks of osteonecrosis of the jaw, Defendant's motion must be denied.

III. Plaintiff Has Introduced Sufficient Evidence To Meet Her Burden On Proximate Cause

Absolute certainty is not required in order for a plaintiff to prove a causal connection between a defendant's acts or omissions and plaintiff's injuries. See *Howard v. Missouri Bone & Joint Ctr, Inc.*, 615 F.3d 991, 996 (8th Cir. 2010) (citation omitted); *Griggs v. Firestone Tire & Rubber Co.*, 513 F.2d 851, 861 (8th Cir. 1975). As the court in *Griggs* explained, "[c]ases involving an alleged failure to warn typically involve the element of forecasting what another's conduct would have been under supposed circumstances; certainty in such a forecast is not required." *Griggs*, 513 F.2d at 861.

Instead, a plaintiff makes a "submissible case . . . if substantial evidence is presented that shows the injury is a natural and probable consequence of a defendant's" acts or omissions. *Id*. In any event, "[a]bsent compelling evidence which establishes the absence of causation, the causation question is for the jury." *Id*.; see also, *Griggs*, 513 F.2d at 861 ("The determination of proximate cause is ordinarily reserved for the jury, and may be shown by circumstantial evidence.")

Plaintiff here has introduced more than sufficient evidence to show that John Brodie's injuries were a natural and probable consequence of the fact that Defendant failed to properly warn of the risk of ONJ. Defendant's motion, therefore, must be denied.

A. Plaintiff Is Entitled to a Heeding Presumption

While Plaintiff must prove proximate cause, Missouri "aids plaintiffs in proving this . . . by presuming that a [proper] warning will be heeded." *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 762 (Mo. 2011) (citations and internal quotations omitted). "In this instance, the term 'presumption' is used to mean 'makes a prima facie case,' i.e., creates

a submissible case that [a proper] warning would have been heeded." *Tune v. Synergy Gas Corp.*, 883 S.W.2d 10, 14 (Mo. 1994). In other words, if Plaintiff is entitled to the heeding presumption, Defendant's motion should be denied.

As the court in *Moore* noted, however, there is "a preliminary inquiry before applying the [heeding] presumption" and that is "whether adequate information is available absent a [proper] warning." *Moore*, 332 S.W.3d at 762 (citations and internal quotations omitted). While Plaintiff has the burden to show the lack of adequate information or prior knowledge, "[n]umerous cases have held that when the defense is raised that the [relevant person] had adequate knowledge of the risks so as to obviate the duty to warn, the question of the adequacy of the knowledge is a question for the jury." *Duke v. Gulf & Western Mfg. Co.*, 660 S.W.2d 404, 418 (Mo. App. W.D. 1983); see also, *Moore*, 332 S.W.3d at 762 (quoting *Duke*).

Based on the evidence introduced at trial thus far, a reasonable jury could find that Dr. Schultz did not have prior knowledge of the true risk of ONJ associated with Zometa. At the time Dr. Schultz prescribed Zometa for John Brodie, he had never seen a case of ONJ. Tr. Vol. 3B at 66:20-25. Whatever understanding Dr. Schultz had about Zometa and the risk of ONJ came primarily from a Zometa label and the Dear Doctor Letter, both of which he claimed to have seen. Tr. Vol. 3B at 54:4-6, 67:9-13.[1] As shown above, however, the August 2004 Zometa Label and Dear Doctor Letter were inadequate. Neither the Label nor the Letter had an actual "warning" about the risk of osteonecrosis of the jaw and, more importantly, neither mentioned a causal association

[1] Of course, Dr. Schultz also testified that package inserts, i.e. labels, change over time and he did not read them every year. Tr. Vol. 3B at 54:7-14. He also admitted that package inserts contain too much information, much of which is not useful. Tr. Vol. 3B at 54:15-22.

between Zometa and osteonecrosis of the jaw or that osteonecrosis of the jaw could occur spontaneously, i.e., without an intervening dental procedure. Of course, the evidence not only shows that the Label and Letter were inadequate, it also shows that they were affirmatively misleading. Both documents contained a list of so-called "well-documented risk factors" for ONJ. In fact, however, the conditions and treatments listed are not risk factors for ONJ and were certainly not well-documented to be risk factors. This list of so-called risk factors may have been particularly misleading in this case because Mr. Brodie did not suffer from most of the medical conditions or take the drugs listed in the Label or the Letter, which may have suggested to Dr. Schultz that it was safe to prescribe Zometa (assuming Dr. Schultz actually saw this list).

While Dr. Schultz claimed that he was aware of the risk of osteonecrosis of the jaw when he first prescribed Zometa to Mr. Brodie, he was unable to remember what risks he discussed with Mr. Brodie. Tr. Vol. 3B at 66:9-17. Dr. Schultz did concede, however, that the risk of ONJ was not foremost on his mind when he started John Brodie on Zometa. Tr. Vol. 3B at 67:5-8. In any event, both John and Sharon Brodie testified explicitly that Dr. Schultz never mentioned any risk of ONJ to John before starting the Zometa. Tr. Vol. 5 at 84:6-13; Tr. Vol. 2A at 70:1-12. Dr. Schultz did admit that he never recommended that Mr. Brodie have a dental examination before starting Zometa and never told John to avoid dental procedures while on Zometa. Tr. Vol. 3B at 75:7-76:21. A reasonable jury could conclude that Dr. Schultz would have warned Mr. Brodie about the risk of osteonecrosis of the jaw if he was aware of it and that Dr. Schultz's failure to warn Mr. Brodie proves he did not know of the risk.

Because Plaintiff is entitled to a heeding presumption that a proper warning would have been followed and, for the reasons discussed below, Defendant cannot rebut that presumption, Defendant's motion must be denied.

B. A Reasonable Jury Could Find That With Better Information, Dr. Schultz Would Have Acted Differently

The trial testimony and the documentary evidence demonstrate that despite Dr. Schultz's testimony to the contrary, an adequate warning would have altered his care and treatment of John Brodie. More specifically, Dr. Schultz's decision not to put John back on Zometa after the May 6, 2006 jaw replacement surgery proves that Dr. Schultz not only would have altered his prescription practice, but did alter his practice.

On February 5, 2005, Dr. Schultz saw John Brodie for the first time. At that visit, Dr. Schultz noted that John was complaining of bone pain and had rapidly progressing metastatic prostate cancer, specifically Stage IV carcinoma with metastases to the bone. According to Dr. Schultz, the metastases had spread to John's hip, spine and ribs, despite prior treatment, including radiation, by other doctors. Tr. Vol. 3B at 79:15–80:4 and 80:17-25.

Dr. Schultz testified that he cannot cure patients who are in John's condition. His goal for John was to "try and make him feel better, feel better longer and live as long as he can feel good." Tr. Vol. 3B at p. 81:3-5. To do that, Dr. Schultz changed certain medications that John was then taking. He also prescribed Zometa. Tr. Vol. 3B at p. 81:17–18.

Dr. Schultz provided ample testimony about the various benefits of Zometa. For example, when asked why he prescribed Zometa to John, Dr. Schultz, referring to his chart note, stated:

> He has bone metastatic disease. The addition of Zometa will decrease the chances for future skeletal events and delay the next skeletal event for this patient.

Tr. Vol. 3B at p. 81:19–23. Dr. Schultz was further asked to confirm that Zometa reduces pathological fractures and bone pain, and increases a patient's mobility. Tr. Vol. 3B at p. 82:9–83:4. When asked about the risks and benefits of Zometa in John's case, Dr. Schultz testified that:

> A. [I] thought he had an **overwhelming need** for Zometa more than the risks that he had of ONJ. That was my decision at the time.
>
> Q. So would it be fair to say that you believed that the risks strongly – **the benefits strongly outweighed the risks**?
>
> A. That was my assessment, **yes**.

Tr. Vol. 3B at p. 85:8–13 (emphasis added). For all of these reasons, Dr. Schultz prescribed Zometa to John Brodie.

John received his first Zometa infusion on February 25, 2005, and monthly thereafter. Pl. Exh. 2013, Feb. 25, 2005 Infusion Chart. However, on November 23, 2005, approximately two weeks after his November 11, 2005 infusion, John telephoned Dr. Schultz's office complaining of jaw pain. Dr. Schultz immediately stopped John's Zometa treatment and referred him to a head and neck surgeon. Tr. Vol. 3B at p. 84:8–17. Dr. Schultz testified that he never prescribed Zometa for John after November 2005. Tr. Vol. 3B at p. 57:2–3.

Dr. Schultz continued to care for John and testified that John's cancer progressed after November 2005. Likewise, John's osteonecrosis of the jaw progressed. That led to a December 21, 2005 debridement procedure by Dr. Boyd, but when that procedure failed

to resolve John's jaw problem, massive reconstruction surgery became necessary. John had that surgery in May 2006. During that surgery, John's lower jaw was replaced with part of his fibula. Tr. Vol. 3A at p. 93:24-96:7.

The May 6, 2006 jaw replacement surgery performed by Dr. Haughey alleviated John's osteonecrosis of the jaw. During the surgery, Dr. Haughey removed 14 centimeters of exposed, damaged (necrotic) bone and replaced it with a piece of John's fibula. Tr. Vol. 3A at p. 94:23-95:7. Following that surgery, John no longer had exposed bone and his jaw pain was reduced. Tr. Vol. 3A at p. 98:7-11. Dr. Haughey's chart note from August 30, 2006 states that John's surgery site is well-healed with solid bone. Pl. Exh. 2013, August 30, 2006 note.

Although Dr. Schultz never prescribed Zometa for John again, in the absence of osteonecrosis of the jaw, there was no reason that Dr. Schultz could not put John back on Zometa. In other words, following Dr. Haughey's surgery, the same risk/benefit analysis performed in February 2005 (the risk of osteonecrosis of the jaw v. the benefits of Zometa) would have applied in May 2006 after the jaw replacement surgery, as well as any time after May 2006, up to and including the time of John's death in July 2008. A trier of fact could reasonably infer that Dr. Schultz would have done that analysis and that the result would have been the same as it was in February 2005: that John had an "overwhelming need" for Zometa and that Dr. Schultz would resume John's Zometa treatment. Tr. Vol. 3B at 85:8.

The evidence is to the contrary. Dr. Schultz did not resume John's Zometa infusions after the surgery. He did not do so for the last six months of 2006; he did not do so at any time in 2007; and he did not do so at any time in 2008 before John died in

July. Instead, Dr. Schultz's records show that over the last 26 months that he treated John before John succumbed to prostate cancer, Dr. Schultz never even considered putting John back on Zometa, despite the fact that all of the initial reasons for putting John on Zometa still existed (i.e., making John feel better, living as long as John could feel good and, most importantly, reducing the risk of bone fractures).[2]

A reasonable jury could conclude that Dr. Schultz's conduct demonstrates that he would have heeded a different warning. Confronted with a patient who developed ONJ while taking Zometa, Dr. Schultz elected not to put that patient – John Brodie – back on Zometa once his osteonecrosis was treated and healed. But he did not. Based on this conduct, a reasonable jury could infer that if the August 2004 Zometa Label had included a stronger warning about the causal relationship between Zometa use and osteonecrosis of the jaw, Dr. Schultz would have altered his prescription practice.

[2] While Novartis may argue that the prior episode of osteonecrosis of the jaw influenced Dr. Schultz's decision not to put John back on Zometa, there is absolutely no evidence of that in the record.

CONCLUSION

Plaintiff hereby incorporates by reference the entire trial record (including the testimony, exhibits and Stipulations). Based on that record and for the reasons cited above, Defendant's Rule 50(a) Motion for Judgment as a Matter of Law on all Claims should be denied.

Dated: January 29, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing, **PLAINTIFF SHARON BRODIE'S MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION FOR JUDGMENT AS A MATTER OF LAW**, was furnished by operation of the Court's Electronic Case Filing System on counsel of record in case number 4:10-CV-138 (HEA) on this 29th day of January, 2012.

Respectfully submitted,

/s/ Daniel A. Osborn
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